K003947

MAR 1 3 2001

GE Medical Systems

page 1 of 2

PO Box 414, W-709
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY AND EFFECTIVENESS

- This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- Identification of Submitter
  Larry A. Kroger, Ph.D., 262-544-3894

- Identification of the Product
  Functional Brain Mapping Option

  Manufactured by: GE Medical Systems
  3200 N. Grandview Blvd.
  Waukesha, WI 53188

- Device Description

  The GE Functional Brain Mapping option produces difference images highlighting changes in blood oxygen level dependent (BOLD) images over time. These differences corresponding to changing stimuli presented to patients that are synchronized with scanning. The resulting parametric or activation images are superimposed on structural images from the same patient.

- Indications for Use

  The GE Functional Brain Mapping Option is a software and hardware package that can be used to acquire, process and display the results of BOLD (blood oxygen level dependent) MRI scan studies taken in the presence of synchronized stimuli presented to a person being scanned. When interpreted by a trained physician these results may be useful in the determination of a course of treatment.

- Comparison with Predicate

  The Functional Brain Mapping option software is substantially equivalent to existing scanning, processing and display features included with the GE Signa CVMR System (K980114) and the Advantage Workstation loaded with the Functool Processing Option (K960265).

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The hardware components associated with this option are all electrically isolated from the patient via fiber optic or acoustic connections and as such present no new safety concerns.

° Summary of Studies

The Functional Brain Mapping option was evaluated equivalently to the IEC 601-2-33 International medical equipment safety standard for Magnetic Resonance Systems. Evaluation testing was done to verify the performance of the option which included the software feature tests which focused on verifying that the information displayed and after computation are identical with expected calculations.

° Conclusions

It is the opinion of GE that the Functional Brain Mapping option does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2001

Larry A. Kroger Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
3200 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K003947
Functional Brain Mapping Option For MRI
Dated: December 20, 2000
Received: December 21, 2000
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K030947

Device Name: Functional Brain Mapping option for MRI

Indications For Use:

The GE Functional Brain Mapping Option is a software and hardware package that can be used to acquire, process and display the results of BOLD (blood oxygen level dependent) MRI scan studies taken in the presence of synchronized stimuli presented to a person being scanned. When interpreted by a trained physician these results may be useful in the determination of a course of treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K030947